Atty. Dkt. No. 053466-0365

UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Hiroaki ITO et al.

Title:

A PREVENTIVE OR THERAPEUTIC

AGENT FOR INFLAMMATORY BOWEL DISEASE COMPRISING IL-6 ANTAGONIST

AS AN ACTIVE INGREDIENT

Appl. No.:

10/677,227

Filing Date:

10/3/2003

Examiner:

Prema Maria MERTZ

Art Unit:

1646

Conf. No.:

8597

# INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.56

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

## TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(c), before the mailing date of either a final action under 37 CFR §1.113, a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application.

### RELEVANCE OF EACH DOCUMENT

Any document listed on the attached PTO/SB/08 was cited as being relevant during the prosecution of the corresponding Norwegian application. A copy of the Norwegian Office Action issued on February 21, 2007, is attached listing each document considered relevant by the examiner. An English-language counterpart (C2) of the foreign-language document (C1) has been provided. The balance of the references cited in the Norwegian Office Action are already of record in the present application.

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

### **STATEMENT**

The undersigned hereby states in accordance with 37 CFR §1.97(e)(1) that each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to filing of this Statement.

Although Applicant believes that no fee is required for this Request, the Commissioner is hereby authorized to charge any additional fees which may be required for this Request to Deposit Account No. 19-0741.

Respectfully submitted,

Date April 20, 2007

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PTO/SB/08 (09-06)

Approved for use through 03/31/2007. OMB 0651-0031

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#### INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Date Submitted: April 19, 2007

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| Complete if Known      |                   |   |  |
|------------------------|-------------------|---|--|
| Application Number     | 10/677,227        | - |  |
| Filing Date            | 10/3/2003         |   |  |
| First Named Inventor   | Hiroaki ITO       |   |  |
| Art Unit               | 1646              |   |  |
| Examiner Name          | Prema Maria MERTZ |   |  |
| Attorney Docket Number | 053466-0365       |   |  |

| U.S. PATENT DOCUMENTS |                 |  |                                  |  |  |
|-----------------------|-----------------|--|----------------------------------|--|--|
| Examiner Cite No.1    | Document Number | Publication Date                         | Name of Patentee or Applicant of | Pages, Columns, Lines,<br>Where Relevant |  |
|                       |                 | Number-Kind Code <sup>2</sup> (if known) | MM-DD-YYYY                       | Cited Document                           | Passages or Relevant<br>Figures Appear |
|                       |                 |  |                                  |  |  |
|                       |                 | •  |                                  |  |  |
|                       |                 |  |                                  |  |  |

|                    | Ţ                        |   | FOREIGN PATENT I               | DOCUMENTS   |  |                |
|--------------------|--------------------------|---|--------------------------------|---|--|----------------|
| Examiner Initials* | Cite<br>No. <sup>1</sup> | Foreign Patent Document Country Code <sup>5</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known) | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Documents | Pages, Columns, Lines,<br>Where Relevant<br>Passages or Relevant<br>Figures Appear | T <sup>6</sup> |
|                    | C1                       | JP 9-235276 A   | 09/09/1997                     | Takeda Chemical Ind. Ltd.                           |  |                |
|                    | C2                       | WO 97/24340 A   | 07/10/1997                     | Takeda Chemical Ind. Ltd.                           |  |                |

| NON PATENT LITERATURE DOCUMENTS |                          |  |                |  |
|---------------------------------|--------------------------|--|----------------|--|
| Examiner Initials*              | Cite<br>No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>6</sup> |  |
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|                                 |                          |  |                |  |

| Examiner<br>Signature | Date<br>Considered |  |
|-----------------------|--------------------|--|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.